This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this further delay of the effective date is in the public interest.

Dated: February 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy. [FR Doc. 02–3282 Filed 2–12–02; 8:45 am] BILLING CODE 4160–01–8

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117 [CGD01-02-007] RIN 2115-AE47

Drawbridge Operation Regulations: Harlem River, NY

AGENCY: Coast Guard, DOT. **ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the drawbridge operation regulations for the Madison Avenue Bridge, mile 2.3 and the Macombs Dam Bridge, at mile 3.2, both across the Harlem River at New York City, New York. This temporary rule will allow the bridges to remain in the closed position at various times to facilitate necessary bridge maintenance.

DATES: This rule is effective from February 18, 2002 through February 28, 2003.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–02–007) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Joe Arca, Project Officer, First Coast Guard District, (212) 668–7165.

SUPPLEMENTARY INFORMATION:

Regulatory Information

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation. Good cause exists for not publishing a NPRM and for making this regulation effective in less than 30 days after publication in the **Federal Register**.

These closures are not expected to impact navigation because the vessels that normally use this waterway were designed to fit under the bridges on the Harlem River without requiring bridge openings. There have been no requests to open these bridges for several years. Accordingly, an NPRM was considered unnecessary and the rule may be made effective in less than 30 days after publication.

Background and Purpose

The Madison Avenue Bridge has a vertical clearance in the closed position of 25 feet at mean high water and 29 feet at mean low water. The Macombs Dam Bridge has a vertical clearance in the closed position of 27 feet at mean high water and 32 feet at mean low water. The existing drawbridge operating regulations, listed at 33 CFR 117.789(c), require the bridges to open on signal from 10 a.m. to 5 p.m., after a four-hour advance notice is given.

The owner of the bridges, the New York City Department of Transportation (NYCDOT), requested a temporary final rule to facilitate scheduled maintenance and replacement of electrical and mechanical systems at the bridges. These bridge closures are not expected to effect vessel traffic because there have been no requests to open the bridges for several years. Vessels that can pass under the bridges without openings may do so at all times during these closures.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). This conclusion is based on the fact that keeping the bridges closed should have no impact on navigation because the bridges have not had any requests to open for several years.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612) we considered whether this rule would have a significant economic impact on a substantial number of small entities. "Small entities" comprises small businesses, not-for profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This conclusion is based on the fact that

the closure of the bridges should have no impact on navigation because the bridges have not had any requests to open for several years.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (32)(e) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation because promulgation of changes to drawbridge regulations have been found to not have a significant effect on the environment. A written "Categorical Exclusion

Determination" is not required for this final rule.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. From February 18, 2002, through February 28, 2003, § 117.789 is temporarily amended by suspending paragraph (c) and adding a new paragraph (g) to read as follows:

§117.789 Harlem River.

* * * * :

(g) The draws of the bridges at 103rd Street, mile 0.0, Willis Avenue, mile 1.5, 3rd Avenue, mile 1.9, Madison Avenue, mile 2.3, 145th Street, mile 2.8, Macombs Dam, mile 3.2, the 207th Street, mile 6.0, and the two Broadway bridges, mile 6.8, shall open on signal from 10 a.m. to 5 p.m. if at least a fourhour advance notice is given to the New York City Highway Radio (Hotline) Room; except that the Madison Avenue Bridge, mile 2.3, need not open for vessel traffic from February 18 through May 24, 2002 and the Macombs Dam Bridge, mile 3.2, need not open for vessel traffic from April 2 through June 30, 2002 and from December 1, 2002 through February 28, 2003.

Dated: January 23, 2002.

G.N. Naccara,

Rear Admiral, U. S. Coast Guard, Commander, First Coast Guard District. [FR Doc. 02–3517 Filed 2–12–02; 8:45 am] BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Diego 01-022]

RIN 2115-AA97

Security Zones; Port of San Diego, CA

AGENCY: Coast Guard, DOT. **ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a moving and fixed security zone 100 yards around all cruise ships that enter, are moored in, or depart from the Port of San Diego. This security zone is needed for national security reasons to protect the public and ports from potential subversive acts. Entry into these zones is prohibited, unless specifically authorized by the Captain of the Port San Diego, or his designated representative.

DATES: This rule is effective from 11:59 p.m. PST on November 5, 2001 to 11:59 p.m. PDT on June 21, 2002.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket COTP San Diego 01–022 and are available for inspection or copying at Coast Guard Marine Safety Office San Diego, 2716 North Harbor Drive, San Diego, California, 92101, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Joseph Brown, Port Safety and Security, at (619) 683– 6495.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM, which would incorporate a comment period before a final rule was issued, would be contrary to the public interest since immediate action is needed to protect the public, ports, and waterways of the United States. For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the Federal Register. The Coast Guard will issue a broadcast notice to mariners advising of these new regulations.

Background and Purpose

Based on the September 11, 2001, terrorist attacks on the World Trade Center in New York and the Pentagon in Arlington, Virginia, there is an increased risk that subversive activity could be launched by vessels or persons in close proximity to the Port of San Diego, against cruise ships entering, departing, or moored within the port of San Diego. The terrorist acts against the United States on September 11, 2001, have increased the need for safety and security measures on U.S. ports and waterways. In response to these terrorist acts, and in order to prevent similar occurrences, the Coast Guard has

established a security zone around cruise ships to protect persons, transiting vessels, adjacent waterfront facilities, and the adjacent land of the Port of San Diego. These security zones are necessary to prevent damage or injury to any vessel or waterfront facility, and to safeguard ports, harbors, or waters of the United States near San Diego, California. This zone will be enforced by the official patrol (Coast Guard commissioned, warrant or petty officers) onboard Coast Guard vessels and patrol craft. The official patrol may also be onboard patrol craft and resources of any government agency that has agreed to assist the Coast Guard in the performance of its duties.

Persons and vessels are prohibited from entering into this security zone unless authorized by the Captain of the Port or his designated representative. Each person and vessel in a security zone must obey any direction or order of the COTP. The COTP may remove any person, vessel, article, or thing from a security zone. No person may board, or take or place any article or thing on board any vessel in a security zone without the permission of the COTP.

Pursuant to 33 U.S.C. 1232, any violation of the security zone described herein, is punishable by civil penalties (not to exceed \$27,500 per violation, where each day of a continuing violation is a separate violation), criminal penalties (imprisonment for not more than 6 years and a fine of not more than \$250,000), in rem liability against the offending vessel, and license sanctions. Any person who violates this regulation, using a dangerous weapon, or who engages in conduct that causes bodily injury or fear of imminent bodily injury to any officer authorized to enforce this regulation, also faces imprisonment up to 12 years (class C felony).

This security zone prohibits all vessels and people from approaching cruise ships that are underway or moored near San Diego, California. Specifically, no vessel or person may close to within 100 yards of a cruise ship that is entering, moored in, or departing the Port of San Diego.

A security zone is automatically activated when a cruise ship passes the San Diego sea buoy while entering port and remains in effect while the vessel is moored within in the Port of San Diego, California. When activated, this security zone will encompass a portion of the waterway described as a 100 yard radius around a cruise ship in the Port of San Diego. This security zone is automatically deactivated when the cruise ship passes the San Diego sea buoy on its departure from port. Vessels